

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EISAI CO., LTD., EISAI INC. and
NOVARTIS PHARMA AG,

Plaintiffs,

v.

ROXANE LABORATORIES, INC.,

Defendant.

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C.A. No. _____

COMPLAINT

Plaintiffs Eisai Co., Ltd. and Eisai Inc. (collectively, “Eisai”) and Novartis Pharma AG (“Novartis”) (collectively, “Plaintiffs”), for their Complaint against Defendant Roxane Laboratories, Inc. (“Roxane”), hereby allege as follows:

THE PARTIES

1. Plaintiff Eisai Co., Ltd. is a Japanese corporation having a principal place of business at 6-10 Koishikawa 4-chrome, Bunkyo-ku, Tokyo 112-8088, Japan.
2. Plaintiff Eisai Inc. is a Delaware corporation having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.
3. Plaintiff Novartis is a Swiss corporation having a principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.
4. Upon information and belief, Defendant Roxane is a Nevada corporation having a place of business at 1809 Wilson Road, Columbus, OH, 43228. Upon information and belief, Defendant Roxane manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action concerning the infringement of United States Patent Nos. 6,740,669 (“the ‘669 patent”), 7,750,028 (“the ‘028 patent”) and 8,076,362 (“the ‘362 patent”) (collectively, “the patents-in-suit”). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Roxane by virtue of, *inter alia*, the fact that it has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Eisai Inc., a Delaware corporation. This Court has personal jurisdiction over Roxane for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

8. This Court has personal jurisdiction over Roxane because it has previously been sued in this district and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., GlaxoSmithKline LLC v. Roxane Laboratories, Inc., et al.*, 11-cv-00542; and *Abbott Laboratories and Wisconsin Alumni Research Foundation v. Roxane Laboratories, Inc.*, 10-cv-00998.

9. Upon information and belief, Roxane has received at least 94 approvals from the FDA for drug products since 2006 and sells drug products throughout the United States, including this judicial district.

10. This Court has personal jurisdiction over Roxane by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PATENTS-IN-SUIT

12. On May 25, 2004, the '669 patent, titled "Crystal Modification of 1-(2, 6-Difluorobenzyl)-1H-1, 2, 3-Triazole-4-Carboxamide and its Use as Antiepileptic," was issued. A copy of the '669 patent is attached as Exhibit A.

13. On July 6, 2010, the '028 patent, titled "Crystal Modifications of 1-(2, 6-Difluorobenzyl)-1H-1, 2, 3-Triazole-4-Carboxamide," was issued. A copy of the '028 patent is attached as Exhibit B.

14. On December 13, 2011, the '362 patent, titled "Crystal Modification A of 1-(2, 6-Difluorobenzyl)-1H-1, 2, 3-Triazole-4-Carboxamide and Dosage Forms and Formulations Thereof," was issued. A copy of the '362 patent is attached as Exhibit C.

ACTS GIVING RISE TO THIS ACTION

15. Eisai holds New Drug Application ("NDA") No. 21-911 for oral tablets containing 200 or 400 mg of the active pharmaceutical ingredient rufinamide. Eisai markets and sells these tablets in the United States under the brand name "Banzel[®]."

16. Novartis owns the patents-in-suit. Eisai holds an exclusive license to the patents-in-suit in the United States.

17. Pursuant to 21 U.S.C. § 355(b)(1), the '669, '028 and '362 patents are listed in the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Banzel[®] or its use.

18. Upon information and belief, Roxane submitted ANDA No. 204988 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Roxane's ANDA No. 204988 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of tablets containing 200 and 400 mg of rufinamide ("the Roxane Generic Product") prior to the expiration of the '669, '028 and '362 patents.

19. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Roxane certified in ANDA No. 204988 that the claims of the '669, '028 and '362 patents are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Roxane Generic Product.

20. Plaintiffs received written notification of Roxane's ANDA No. 204988 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter dated June 27, 2013 ("Notice Letter").

21. This action was commenced within 45 days of the Roxane Notice Letter.

FIRST COUNT
INFRINGEMENT BY ROXANE OF U.S. PATENT NO. 6,740,669

22. Plaintiffs re-allege paragraphs 1-21 as if fully set forth herein.

23. In its Notice Letter, Roxane did not allege noninfringement of Claims 1-6, 9-11 and 18 of the '669 patent separate and apart from any assertions regarding the validity of those claims.

24. Roxane's submission of ANDA No. 204988 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '669 patent under 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Roxane Generic Product, if approved by the FDA, prior to the expiration of the '669 patent including its patent term extension, would infringe the '669 patent under 35 U.S.C. § 271.

26. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Roxane's ANDA No. 204988 be a date that is not earlier than the expiration of the patent term extension granted by the USPTO pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '669 patent to which Plaintiffs are or become entitled.

27. Plaintiffs will be irreparably harmed by Roxane's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

28. Upon information and belief, Roxane was aware of the existence of the '669 patent and was aware that the filing of its ANDA and certification with respect to the '669 patent constituted an act of infringement of that patent.

SECOND COUNT
INFRINGEMENT BY ROXANE OF U.S. PATENT NO. 7,750,028

29. Plaintiffs re-allege paragraphs 1-28 as if fully set forth herein.

30. In its Notice Letter, Roxane did not allege noninfringement of Claims 1-8 of the '028 patent separate and apart from any assertions regarding the validity of those claims.

31. Roxane's submission of ANDA No. 204988 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '028 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Roxane Generic Product, if approved by the FDA, prior to the expiration of the '028 patent including its patent term extension, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '028 patent. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Roxane's ANDA No. 204988 be a date that is not earlier than the patent term extension granted by the USPTO pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '028 patent to which Plaintiffs are or become entitled.

33. Plaintiffs will be irreparably harmed by Roxane's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

34. Upon information and belief, Roxane was aware of the existence of the '028 patent and was aware that the filing of its ANDA and certification with respect to the '028 patent constituted an act of infringement of that patent.

THIRD COUNT
INFRINGEMENT BY ROXANE OF U.S. PATENT NO. 8,076,362

35. Plaintiffs re-allege paragraphs 1-34 as if fully set forth herein.

36. In its Notice Letter, Roxane did not allege noninfringement of Claims 1-21 of the '362 patent separate and apart from any assertions regarding the validity of those claims.

37. Roxane's submission of ANDA No. 204988 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '362 patent under 35 U.S.C. § 271(e)(2)(A).

38. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Roxane Generic Product, if approved by the FDA, prior to the

expiration of the '362 patent, would infringe the '362 patent under 35 U.S.C. § 271. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Roxane's ANDA No. 204988 be a date that is not earlier than the expiration of the '362 patent, or any later expiration of exclusivity for the '362 patent to which Plaintiffs are or become entitled.

39. Plaintiffs will be irreparably harmed by Roxane's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

40. Upon information and belief, Roxane was aware of the existence of the '362 patent and was aware that the filing of its ANDA and certification with respect to the '362 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. Roxane has infringed one or more claims of the '669 patent;
- B. Roxane has infringed one or more claims of the '028 patent;
- C. Roxane has infringed one or more claims of the '362 patent;
- D. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Roxane's ANDA No. 204988 shall not be a date that is earlier than the latest expiration date of the patents-in-suit, including any applicable exclusivities or extensions;
- E. That Roxane, its officers, agents, servants and employees, and those persons acting in concert, participation, or in privity with any of them, and their successors or assigns, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing into the United States the Roxane Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims

of the '669, '028, or '362 patent prior their expiration, including any exclusivities or extensions to which Plaintiffs are or become entitled;

F. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur in prosecuting this action; and

G. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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